

NEWSLETTER

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GERMAN REGULATORY AFFAIRS – BVL APPLICANTS CONFERENCE 2015

SPECIAL EDITION

Dear Subscribers,

This edition of the Newsletter comprises a detailed report on the last BVL Applicants Conference held in Braunschweig on 16 June 2015.

As a main topic the representatives of authorities addressed the point how to optimise the registration procedures. Furthermore, the new dRR templates were discussed and the current status of evaluation of plant protection products was presented in this event.

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As always, we appreciate your feedback and comments regarding the SCC Newsletter.

Please drop us an

E-mail at newsletter@scc-gmbh.de.

Finally, I would like to wish you nice holidays and look forward to seeing you at the CIR in Barcelona in September 2015.



Dr. Friedbert Pistel

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CIR Chemical Industries Regulations 23-24 September 2015, Barcelona, Spain

SCC GmbH is a sponsor for this 15th annual AgChem Forum 2015 which will be held in Barcelona.

We are delighted to announce that our President, Dr. Friedbert Pistel, will be present at this event.

Furthermore, Dr. Bernd Brielbeck, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides, will make a presentation about “Biopesticides - do they exist in EU legislation?” and Dr. Norbert Weißmann, Senior Manager Regulatory Affairs, Agrochemicals and Biopesticides – Efficacy, will also be participating in the conference.

Meet with them on the exhibition stand no. 15 to discuss your needs in registrations of Agrochemicals and Biopesticides, but also for any other business matters.



AGROCHEMICALS

**BVL Applicants Conference,
Braunschweig 2015**

During the applicants conference at the BVL on 16 June 2015 representatives of the BfR, UBA and JKI gave presentations on how to optimise the registration procedures. All three speakers identified the harmonisation of the application areas, especially of the critical application areas forming the risk envelop, as important for harmonisation. Dr. Stein from BfR identified the basis for this harmonisation of the GAP in the efficacy and residue sections. In previous applications he also saw a difference between the GAPs for Germany and the rest of the zone, particularly if modification to suit the needs of Germany was made. Furthermore, addressing each application point with clear references and cross-references is important. References to applications which are intended in the future must not be made. Each application should be seen as a full stand-alone document. All three speakers identified the new dRR format, which is applicable as of 1 January 2016, as an important step towards accepting the evaluation of the zonal Rapporteur Member State and a general consent among the Member States as to the acceptance of their mutual evaluations.

Dr. Stein of the BfR, in addition, identified the toxicity of the co-formulants as an important issue. The applicant is obliged to provide updated, with respect to date and contents, MSDSes for each co-formulant. He indicated that the ECHA database often contains contradicting information on the same co-formulant. It is the obligation of the applicant to identify which co-formulant is actually contained in his formulation. A choice of a co-formulant with a less stringent classification must be justified. Furthermore, in the future BfR sees cut off criteria, multiple residues exposures, the different exposures to workers and bystanders and cumulative risk assessments as important issues to be addressed by the applicant.

Dr. Felsmann of the UBA emphasised that in the pre-meeting no final evaluation of studies or a risk assessment can be conducted. Nevertheless, a final GAP should be available for that meeting. In addition, she

requested that study summaries should also be provided for all studies which are post-submitted. She then detailed some national particularities which are to be reported and calculated in the national addendum for Germany.

Dr. Engelke of JKI especially endorsed the new dRR templates, which were noted on 20 March 2015 in the standing committee and which are applicable as of 1 January 2016. The efficacy section has been moved from B7 to B3. The GAP is only contained in the new section B0. The templates are available from the BVL homepage in two different versions, one containing macros the other one not. He emphasised that the GAP table must be fully filled in and all information must be clearly given. As guidance EPPO PP1/240 and PP1/248 must be used. Furthermore, the GAP information must be identical to the information given in the application form and the label. Pests must be identified by their scientific name and EPPO codes. An EPPO global database is available under <https://gd.eppo.int/>. Where Germany is the zonal Rapporteur and has to evaluate applications not common to German agriculture, the real application practices should be described in detail to enable the German evaluators to assess the application properly. With respect to the data requirements, he emphasised that sufficient data are to be provided for all crops and for all climatic zones where applications are made to. Also, in the case of re-authorisation, if such data is not yet available. The BVL has provided a checklist to applicants on their homepage to enable complete applications of good quality. Pre-submission meetings are possible prior to submission of applications with the BVL, but also directly and in parallel with the JKI. In addition the JKI also offers technical meetings well in advance to submission of data to discuss the GAP and the intended efficacy programme.

In the subsequent discussion the BVL conceded that with a new dRR format the reference lists contained in that format are the only reference lists which the BVL will request. The old German lists are no longer required.

Dr. Puclik-Günther (BVL) gave a presentation on the aerial application of plant protection products. The legal base is Regulation 2009/128/EU which is transcribed into the German Plant Protection Act. § 18(3). Aerial applications are only allowed in steep slope vineyards and the top area of woods. Prerequisite for such applications are an authorisation for the use with common application equipment. Subsequently, a special application has to be filed with the BVL to apply by aerial crafts and then again a further application has to be filed with the Federal Authorities for

the application in a geographic area. The list of plant protection products allowed for aerial applications are published in the Federal register.

The German authorities are currently still working on the 91 applications under Directive 91/414, as detailed by Dr. Savinski of BVL in his presentation. Under Regulation 1107/2009, 217 applications with Germany as a zonal Rapporteur Member State are being evaluated. 235 applications are under evaluation where Germany is concerned Member State. In both latter cases a significant increase of applications, as from 2014, has been observed. Mutual recognitions have increased slightly to 26, currently. This adds up to total of 478 zonal applications where Germany is involved, a significant increase from 349 at the same time in 2014. The applications for minor uses have only slightly increased to 154.

The prescribed evaluation time periods are, in general, not kept by Germany, it was conceded. The major problems are insufficient harmonisation, missing acceptance of the evaluation of the zonal Rapporteur, the required high quality of the dRR and the discussions with the other Member State. Also, delays in post-submissions and unclear and imprecise applications have been identified to cause delays. The BVL intends to overcome them by a number of measures, such as a very strict stop of the clock period of six months only, a more intensive fine-tuning with Authorities and Ministries within Germany, a more intensive completeness check in the beginning and rejection of incomplete applications and, finally, the requirement for applicants to check against available checklists.

For 2016, BVL expects 122 additional product applications containing AIR 2 active substances. For 37 of these applications Germany is expected to be zonal Rapporteur Member State. The workload will be further increased due to the comparative assessment.

Dr. Puclik-Günther of BVL then presented the comparative assessment as implemented by the BVL. It is based on paragraph 50 of Regulation 1107/2009 and will become obligatory for applications submitted as of 1 August 2015. The evaluation is done by each Member State. Two guidelines are the basis of this assessment: EPPO PP1/271 and SANCO/11507/2013 rev. 13. Germany's approach is designed after these Guidance Documents as well as the draft documents available from UK and Austria. The evaluation will be integrated in the normal registration procedure and will not extend the time period of that evaluation. Additional fees of up to 3225 Euros (in exceptional cases) are required. The applicant has to place the pertinent information into the dRR Part A, as it is a

strictly national issue. As to the CADDY version of the dossier, the information should be contained in document N or as an Appendix to the application form. In the pre-evaluation, the BVL will initially identify potentially substitutionable uses. These will then be passed on to the JKI, which will try to identify practical alternatives and thus solidify the evaluation that a given use might be substituted. In the next step, BfR and UBA will evaluate these uses against the alternatives identified by JKI. A final management phase will be done by BVL. Uses for the ecological farming according to Regulation 834/2007 Appendix 2 are exempted from the comparative assessment. Also, minor users are exempted.

For resistance management, Germany requires a minimum of three active substances with different modes of action, which have not yet shown any resistance. The alternative should only substitute a use, where a significantly reduced risk is identified and where no other risk is increased. Finally, the speaker emphasised that those criteria are still under discussion and changes might be necessary as first experiences are gained.

The whole complex of Article 43, re-authorisations, was presented by Dr. Savinski of BVL. Currently, there is no final EU Guidance Document, but draft version 13 of the pertinent Guidance Document has just been released and will be the basis for a final decision expected on 13/14 July 2015 in the standing committee. In Germany the re-authorisation procedure is detailed in the two approaches ZV2 (Germany as zonal Rapporteur) and ZV4 (Germany as concerned Member State). The speaker emphasised a significant difference between the authorisations in Germany which have been issued under the zonal procedure and those previously issued under Directive 91/414.

In the zonal procedure the authorisation of a plant protection product is directly related to the approval of the active substance. Thus, if the approval is postponed, the authorization of a respective plant protection product will be extended until the active substance is approved (plus one year for product authorisation). In the latest version of the Guidance Document it is newly stipulated that a notification is expected from the applicant two months after the EFSA conclusion for the active substance is available. This notification must contain intended studies and a timeframe as to when the reports of these studies are expected. As previously, the application has to be submitted to the Member States three months after entry into force of the active substance approval.

For authorisations currently in force in Germany under Directive 91/414 with an expiry date after re-approval of the active substance, a voluntary application under Article 43 can be placed with the authori-

ties. If not, the German authorities will check the existing authorisation against the new end points of the active substance re-approval and, if no concern is raised, the authorisation will continue until its previously prescribed expiry date. A voluntary application under Article 43 is nevertheless strongly recommended, to receive another full term of authorisation. If the existing Directive 91/414 authorisation expires before the re-approval of the active substance, a new application (i.e. ZV1 / ZV3 not: re-authorisation (ZV2 / ZV4)) must be placed with the BVL one year before the expiry date, at the latest! An exception is made for AIR 2 containing plant protection products, where applications to Germany can be placed until 31 March 2016, to harmonise the German authorisation dates with the authorisation dates of products in other Member States.

Zonal authorisations which expire shortly before the active substance re-approval, must be re-applied for under article 43 before they expire. All ongoing evaluations will be evaluated after active substance re-approval according to the new end points which might have been determined in the re-approval procedures. The data requirements for Article 43 procedures are the new requirements from the active substance re-approval. A fully filled in dRR must be submitted, with the new data highlighted. The efficacy section can be reduced to resistance management assessment, if the GAP remains unchanged. Also important is proof that the applicant has full access to all new active substance data.

In Article 43 applications no new uses must be introduced and a modification of the GAP can only be accepted, if it is required due to changed endpoints in the active substance re-approval. These modifications have to be justified and can only be introduced at the time of application; no changes will be accepted during the evaluation. Formulation changes must not be made, except for minor changes according to the respective Guidance Document. For post-submissions of data required due to the active substance approval the final Guidance Document should be consulted.

In the re-authorisation procedure, also Article 51 applications (minor uses) must be re-applied for.

Ms. Seng of BVL described the obligatory notification of the amount of active substances and products being sold in Germany as detailed in Paragraph 64 of the German Plant Protection Act. All pertinent information can be found at the following links and homepages.

Sales volume:

www.bvl.bund.de/psmstatistiken

Application rate, treatment index:

<http://papa.jki.bund.de/>

The use of plant protection products in the European Union (1992-2003):

http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-76-06-669/EN/KS-76-06-669-EN.PDF

EU-sales volume 1980-2008:

http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=aei_fm_salpest&lang=de

EU-sales volume 2011:

http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=aei_fm_salpest09&lang=de

FAOSTAT: „Pesticide Use“:

<http://faostat3.fao.org/browse/R/RP/E>

OECD Environmental Database:

http://stats.oecd.org/viewhtml.aspx?datasetcode=TA_D_ENVINDIC_2013&lang=en

The new plant protection product application management system of the European Commission has been described by Dr. Joermann of the BVL. There is an obligation from Article 57 and Article 76 of Regulation 1107/2009 to provide such a data base to support the application work in the zonal system. Applicants are required to enter the basic data and, subsequently, authorities are to update the status of the evaluation. Finally, after authorization, the information on the authorised product, including the GAP, is entered and put into the public domain. Currently, the entries into the database are voluntary, but are intended to be obligatory as of 2016. Before being able to supply information to the database, applications have to be made to the Commission to be assigned password and login details. Handbooks are available as well as a helpdesk under: santeppadim@ec.europa.eu.



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